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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/643,649	08/18/2003	Jack Chu	PA1515 (MEDT/0018)	5247

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EXAMINER	
NEAL, TIMOTHY J	

ART UNIT	PAPER NUMBER
3731	

DATE MAILED: 08/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/643,649	CHU ET AL.	
	Examiner	Art Unit	
	Timothy J. Neal	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 August 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 November 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *see attached*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Information Disclosure Statements Mail Dates:
11/29/2004
01/02/2004
12/17/2003

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DETAILED ACTION

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the two helices (claim 2), three helices (claim 3), the microspheres (claim 28), and the two therapeutic coatings separated by a second coating (claim 35) must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner,

the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

Claim 18 is objected to under 37 CFR 1.75(c) as being in improper form because a dependent claim should refer to a proceeding claim. See MPEP § 608.01(n). Accordingly, the claim has not been further treated on the merits.

Claim 19 is objected to under 37 CFR 1.75(c) as being in improper form because a dependent claim shall not refer back to a claim that is held under objection as being in improper form. See MPEP § 608.01(n). Accordingly, the claim has not been further treated on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 30 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 30 recites the limitation "the spray" in the first line of the claim. There is insufficient antecedent basis for this limitation in the claim. The recitation of “the spray”

may refer to claim 32, which recites "a spray". The Examiner has thus interpreted "the spray" to mean "a spray".

Claim 37 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 37 recites the limitation "the polymer" in the first line of the claim. There is insufficient antecedent basis for this limitation in the claim. The Examiner is unable to determine what "the polymer" refers to. "The polymer" may refer to the material of the stent or the coating. The Examiner has interpreted "the polymer" to refer to "the coating" in claim 36.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, 6-12, 17-19, 31, 34-37, 40, and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by Ragheb et al. (U.S. 6,096,070).

Regarding **claim 1**, Ragheb et al. discloses a stent (Fig. 1 Item 12) locatable interior of an aneurysmal site in a blood vessel; wherein the stent supports the aneurysmal site upon deployment, contracts when the aneurysmal site contracts, and comprises at least one therapeutic agent (Col 3 Lines 26-39).

Regarding **claim 2,** Ragheb et al. discloses the stent having a helical configuration (Col 6 Lines 39-42 and Col 15 Line 56).

Regarding **claim 3,** Ragheb et al. discloses the stent comprising at least one helix (Col 6 Lines 39-42 and Col 15 Line 56).

Regarding **claim 6,** Ragheb et al. discloses the stent being self-expandable (Col 6 Line 65).

Regarding **claim 7,** Ragheb et al. discloses the stent comprising a polymer (Col 7 Lines 29-47).

Regarding **claim 8,**Ragheb et al. discloses the polymer being biodegradable (Col 7 Lines 29-47).

Regarding **claim 9,** Ragheb et al. discloses the polymer being cellulose acetate (Col 7 Lines 29-47).

Regarding **claim 10,** Ragheb et al. discloses the therapeutic agent being covalently linked to the polymer (Col 8 Line 25).

Regarding **claim 11,** Ragheb et al. discloses the polymer being not biodegradable (Col 7 Lines 29-47).

Regarding **claim 12,** Ragheb et al. discloses the polymer being polyurethane (Col 7 Lines 29-47).

Regarding **claim 17,** Ragheb et al. discloses the stent comprising metal (Col 7 Lines 29-47).

Regarding **claim 18,** Ragheb et al. discloses the metal being a metal alloy (Col 7 Lines 29-47).

Regarding **claim 19,** Ragheb et al. discloses the metal alloy being NiTi (Col 7 Lines 29-47).

Regarding **claim 31,** Ragheb et al. discloses the therapeutic agent being applied as a coating to the stent (Abstract and Column 7 Lines 55-62).

Regarding **claim 32,** Ragheb et al. discloses the coating being applied as a film (Col 18 Line 2).

Regarding **claim 34,** Ragheb et al. discloses a second coating deposed over the therapeutic coating (Fig. 2 Item 20).

Regarding **claim 35,** Ragheb et al. discloses at least two therapeutic coatings, wherein each therapeutic coating is separated by a second coating (Fig. 2 Items 18, 22, and 24).

Regarding **claim 36,** Ragheb et al. discloses the coating being a biodegradable coating (Col 9 Lines 20-67).

Regarding **claim 37,** Ragheb et al. discloses the polymer being heparin (Col 9 Line 23).

Regarding **claim 38,** Ragheb et al. discloses the coating being a time release coating (Col 10 Lines 30-35).

Regarding **claim 40,** Ragheb et al. discloses the stent being formed by laser cutting (Col 16 Line 51).

Regarding **claim 41,** Ragheb et al. discloses the stent being deployed by a catheter (Col 10 Line 63).

Regarding **claim 43**, Ragheb et al. discloses a helical stent locatable interior of an aneurysmal site in a blood vessel; wherein the stent supports the aneurysmal site upon deployment, contracts when the aneurysmal site contracts, and comprises at least one therapeutic agent (Col 19 Lines 22-27).

Regarding **claim 44**, Ragheb et al. discloses the stent being biodegradable (Col 7 Lines 29-47).

Regarding **claim 45**, Ragheb et al. discloses the stent comprises poly(orthoester) (Col 7 Lines 29-47).

Claims 1, 31, 38, and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Hunter et al. (U.S. 5,716,981).

Hunter discloses coated stents, wherein the coating comprises a polymer and a therapeutic agent (Column 1, Lines 14-16). Hunter also discloses polymers including polytlactic acid) and polycaprolactone (column 7); microsphere and size ranges of up to approximately 120 microns (figures 5-6, 9-10), and release profiles of the therapeutic

agent including about 1% to about 25% of the therapeutic agent released in the first 10 days (figure 15D).

Claims 42 and 46 are rejected under 35 U.S.C. 102(e) as being anticipated by Gerberding (U.S. 6,790,224).

Gerberding discloses a method of treating an aneurysm comprising deploying the device of claim 1 in an aneurysmal site (Fig. 2).

Gerberding also discloses deploying a stent graft to exclude the aneurysm the a substantial portion of device of Claim 1 being disposed between the stent graft and the wall of the aneurysm (Fig. 2 Items 16 and 18).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ragheb et al. in view of Solem et al (U.S. 6,210,432).

Ragheb et al. discloses the invention substantially as claimed as stated above.

Regarding **claims 4 and 5**, Ragheb et al. does not disclose the stent having a helical configuration, the stent comprising at least one helix, the stent comprising two helices, or the stent comprising three helices. Solem et al. teaches a stent comprising two helices (Fig. 3) and comprising three helices (Col 3 Lines 41-43). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Ragheb et al.'s stent to include Solem et al.'s helix configurations. Such a modification would allow the stent to bend as necessary.

Claims 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ragheb et al. in view of Eisert (U.S. 2005/0192664).

Ragheb et al. discloses the invention substantially as claimed as stated above.

Regarding **claims 13and 14**, Ragheb et al. does not disclose the polymer being a pH-sensitive polymer. Eisert teaches a pH sensitive polymer (Paragraph 64) that expands when contacted with a certain pH. Eisert does not name the polymers listed in claim14, however, the polymers listed in claim 14 are well known in the art to be temperature sensitive polymers. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Ragheb et al.'s polymer stent to include Eisert's pH-sensitive polymer. Such a modification would allow the stent to expand.

Regarding **claims 15 and 16**, Ragheb et al. does not disclose the polymer being a temperature-sensitive polymer. Eisert teaches a temperature sensitive polymer (Paragraph 65) that takes on a new shape when heat is applied. Eisert does not name the polymers listed in claim16, however, the polymers listed in claim 16 are well known

in the art to be temperature sensitive polymers. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Ragheb et al.'s polymer stent to include Eisert's temperature sensitive polymer. Such a modification would allow the stent to change shape upon application of heat.

Claims 20-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ragheb et al.

Ragheb et al. discloses the invention substantially as claimed as stated above.

Ragheb et al. does not disclose the therapeutic agents claimed in claims 20-27. However, the agents claimed in claims 20-27 are well known in the art and well known in the art for the treatment of various vascular deficiencies. Ragheb et al. discloses the stent being coated with a therapeutic agent. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Ragheb et al.'s therapeutic agent to include the agents claimed in claims 20-27. Such a modification would apply therapeutic agents at the site of injury.

Claims 28-30 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ragheb et al. in view of Sparer et al. (U.S. 2004/0127978).

Ragheb et al. discloses the invention substantially as claimed as stated above.

Regarding claim 28, Ragheb et al. does not disclose the therapeutic agent being contained in a microsphere associated with the polymer. Sparer et al. teaches the therapeutic agent being contained in a microsphere associated with the polymer (Paragraph 88). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Ragheb et al.'s therapeutic agent

to be contained in Sparer et al.'s microsphere. Such a modification allow for more precise control over release of the agent.

Regarding claim 29 and 30, Ragheb et al. does not disclose the microspheres being about 50 nm to 500 micrometers in size or between 0.1 micrometers to about 100 micrometers in size. Sparer et al. teaches the microspheres being about 50 nm to 500 micrometers in size (Paragraph 88) and being applied as a spray (Paragraph 97). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Ragheb et al.'s therapeutic agent to be contained in Sparer et al.'s microspheres of the given dimensions. Such a modification would allow for control over the release of the agent.

Regarding claim 39, Ragheb et al. does not disclose the time release coating releasing from about 1% to about 25% of the therapeutic agent within 10 days after deployment. Sparer et al. teaches the time release coating releasing from about 1% to about 25% of the therapeutic agent within 10 days after deployment (Fig. 1). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Ragheb et al.'s coating to include Sparer et al.'s release characteristics. Such a modification would allow the agent to be applied to the deficiency over a period of time and not all at once.

Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ragheb et al. in view of Tartaglia et al. (U.S. 5,637,113).

Ragheb et al. discloses the invention substantially as claimed as stated above.

Regarding claim 28, Ragheb et al. does not disclose the film being from 10 micrometers to 5 millimeters thick. Tartaglia et al. teaches a therapeutic coating consisting of a film from 0.0015 inch to 0.002 inch thick (Col 7 Line 40). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Ragheb et al.'s coating to include Tartaglia et al.'s film of given dimensions. Such a modification would make the film thin enough so as to not add significant dimension to the stent.

Claim 47 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gerberding in view of Falotico et al. (U.S. 2003/0060877).

Gerberding discloses the invention substantially as claimed as stated above.

Gerberding does not disclose the method wherein the therapeutic agent is inactive until it comes in contact with an activating agent. Falotico et al. teaches a therapeutic agent being inactive until it comes in contact with an activating agent (Paragraph 142). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Gerberding's agent to include the activation characteristic of Falotico et al. Such a modification would allow for additional measure of time release.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Brown (U.S. 2003/0004141) discloses a therapeutic coating on a

stent. Buscemi et al. (U.S. 5,500,013) discloses a helical stent for drug delivery. Hanson (U.S. 6,375,242), Horvath et al. (U.S. 6,663,863), Thompson et al. (U.S. 5,834,449), Hossainy et al. (U.S. 6,153,252), Brazzell (U.S. 2001/0039438), and Wright et al. (U.S. 6,273,913) disclose various drugs for coating stents.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy J. Neal whose telephone number is (571) 272-0625. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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7/24/06